AUG 16 2004

K041461

APPENDIX I: SUMMARY OF SAFETY AND EFFECTIVENESS
For
KMI Distal Volar Radius Plate System

1. **Submitter:**
Kinetikos Medical, Inc.
6005 Hidden Valley Rd.
Carlsbad, CA 92009

Contact Person:
John G. Spampinato
V.P., Quality Assurance
Kinetikos Medical, Inc.
6005 Hidden Valley Road
Carlsbad, CA 92009
(448) 760 1706
FAX (448) 760 1739

Date Prepared: May 29, 2004

2. **Trade Name:** KMI Distal Volar Radius Plate System
Common Name: Distal Volar Radius Fracture Repair System
Classification Name: Single, multiple component Metallic Bone Fixation Appliances and Accessories, per 888.3030

3. **Predicate or legally marketed devices which are substantially equivalent**

-Hand Innovations Distal Volar Radius Fracture Repair System (K002775)

4. **Description of Device**
This fixation device is intended for use in the reduction, stabilization, and internal fixation of proximal radial bone fractures. The design incorporates the use of a plate and two sets of bone screw sets that are fixated perpendicular. The implant utilizes 'variable angle locking technology' (VALT) screw locking system which facilitates precise angular positioning of the bone screws relative to the distal volar radius plate.

Materials: Titanium; Ti-6A14V-ELI as per ASTM F136

Function: The system functions to fix proximal radial bone fractures together, thereby facilitating fixation.

5. **Intended Use**
The use of the KMI Distal Volar Radius Plate is generally indicated for the reduction and fixation of fractures of the distal radius bone. It is indicated for use in the fixation of fractures classified as acute or fresh, as well as cases of non-union where conservative treatment options have failed. Use of the implant is contraindicated in those cases where complete avascular necrosis has rendered bone stock inadequate.

6. **Comparison of technological characteristics of the device to predicate and legally marketed devices:**
There are no significant differences between the KMI Distal Volar Radius Plate and other systems currently being marketed which would adversely affect the use of the product. The KMI Distal Volar Radius Plate employs the same basic mechanical features as the predicate, legally marketed device specified in section I in that the essential configuration consists of a plate and sets of bone screws intended for use in the reduction of fractures of the distal proximal radius bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Mr. John G. Spampinato
Vice President, Quality Assurance
Kinetikos Medical, Inc
6005 Hidden Valley Road
Carlsbad, California 92009

Re: K041461
Trade/Device Name: KMI Distal Volar Radius Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: May 29, 2004
Received: June 2, 2004

Dear Mr. Spampinato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041461

Device Name: KMI Distal Volar Radius Plate

Indications For Use:

The KMI Distal Volar Radius Plate is generally indicated for the reduction, stabilization and internal fixation of proximal radius bone fractures and osteotomies involving the distal radius.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041461